

MAR - 4 1997

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K65176

1. Submitter's Name, Address and Telephone Number, and Contact Person:

Miss Karenann J. Brozowski
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Telephone Number: (603)532-7706

Contact Person:

Miss Karenann J. Brozowski

2. Name of the Device, including the trade or proprietary name if applicable, and the common name, and the classification name, if known;

Trade Name: Pilling Weck 2-Piece Take-Apart Instruments

Common Name: Endoscopic Forceps/Graspers/Scissors

Classification Name: Endoscopic and Accessories

3. Identification of the legally marketed device that the submitter claims equivalence.

The devices in consideration are substantially equivalent to the devices currently marketed by Karl Storz Endoscopy America, Inc. Under 510(k) K952149.

4. A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or the promotional material of the device.

The Pilling Weck 2-Piece Take-Apart Instrumentation are endoscopic instruments, which have jaws designed to cut, grasp, dissect, retract, and manipulate. The reusable handles are offered in both insulated and noninsulated actuating rings that adapt to various interchangeable jaw configurations with integral shafts. The shaft of the jaws fits into the handle and can be taken apart for cleaning. The jaws are rotated by turning the knob on the handle.

5. A statement of the intended use of the device that this the subject of the premarket notification submission:

The Pilling Weck 2-Piece Take-Apart Instrumentation is designed to be used endoscopically through cannulae to perform cutting, grasping, dissecting, retracting, and manipulating functions.

6. If the device has the same technological characteristics as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to the legally marketed device.

The intended uses of the Pilling Weck 2-Piece Take-Apart Instrumentation and the Karl Storz Endoscopy America, Inc. Devices under K952149 have the same intended use, and that is for endoscopy procedures through cannulae for cutting, grasping, dissecting, retracting, and manipulating.

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The devices have reusable handles that accommodate inserts, that can be rotated 360 Degrees during use.

Both devices include insulated and noninsulated handles, and accommodating shafts.

In the Pilling Weck device there is included a flushing port to facilitate cleaning. This port is not present on the Karl Storz devices.

All Pilling Weck device handles adapt the interchangeable working ends by inserting them through the inner diameter of the shaft that is an integral part of the handle. The fit is secured by a detented proximal end that locks securely in place by encapsulation with the actuation of a push button. In some of the Storz instruments, security is achieved by a one-quarter turn into the outer tube and then connecting into the outer tube handle. The rest of the Storz instruments are the same as Pilling Weck.